

901 E. 233rd Street Carson, California 90745-6204 310/835-8400 Eax 310/835-6615

March 13, 1998

3 U 4 5 '98 MAR 31 P3:08

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204



Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statements:

Promotes Healthy Brain Function

DHA (Docosahexaenoic Acid) is naturally produced by the body, but may require supplementation to reach proper levels. DHA is required for normal brain development and is the primary structural fatty acid in the gray matter of the brain and retina of the eye. DHA is necessary for proper mental and visual functioning. Research suggests that DHA may be important for signal transmissions among cells in the brain, eye and nervous system.

In the United States DHA levels can be low as a result of poor dietary habits. Your Life® DHA dietary supplement may help raise DHA levels in the blood when taken regularly on the following product:

YourLife® DHA

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Regulatory Affairs Associate

> 51095 LGT 1435